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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,893	09/28/2001	Alessandra D'Azzo	SJ-01-0020	4347

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EXAMINER	
FRONDA, CHRISTIAN L	
ART UNIT	PAPER NUMBER
1652	4

DATE MAILED: 02/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/966,893	Applicant(s) D'Azzo et al.
	Examiner Christian L. Fronda	Art Unit 1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1-20 are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐	Notice of References Cited (PTO-892)	4) ☐	Interview Summary (PTO-413) Paper No(s).
2) ☐	Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) ☐	Notice of Informal Patent Application (PTO-152)
3) ☐	Information Disclosure Statement(s) (PTO-1449) Paper No(s).	6) ☐	Other

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, drawn to a method for treating a subject suffering from a lysosomal storage disorder by producing a protein or an active fragment thereof in an insect cell culture and administering a therapeutically effective amount of said protein to said subject, classified in class 424, subclass 178.1.

II. Claim 7, drawn to a method for treating a subject with a protein other than α-galactosidase by producing said protein in an insect cell culture and administering a therapeutically effective amount of said protein to said subject, classified in class 514, subclass 2.

III. Claims 8-13, drawn to a pharmaceutical composition comprising a protein useful for treating a lysosomal storage disorder other than Fabry disease that is selectively imported into macrophages when administered to a subject and a pharmaceutically acceptable carrier wherein said protein is produced in an insect cell culture, classified in class 424, subclass 94.1.

IV. Claims 14-16, drawn to a method for producing a protein, classified in class 435 , subclass 69.1.

V. Claim 17, drawn to a protein-conjugate complex that is selectively imported into macrophages when administered to a subject wherein the protein component of said protein-conjugate complex is produced in an insect cell culture, classified in class 530, subclass 350.

VI. Claim 18, drawn to a method for increasing the ability of a cell to uptake a protein produced in an insect cell culture comprising causing said cell to express a mannose receptor on its membrane, classified in class 514, subclass 44.

VII. Claim 19, drawn to a system for targeting a protein to a desired cell comprising causing said cell to express a mannose receptor on its membrane, producing said protein in an insect cell culture, and contacting said protein with said cell, classified in class 435, subclass 800.

VIII. Claim 20, drawn to a method for purifying a protein produced in an insect cell culture using a Concanavalin A-Sepharose column, classified in class 530, subclass 412.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I, II, IV, VI, and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The processes of Groups I, II, IV, VI, and VIII are distinct both physically and functionally; require different process steps, reagents, and parameters; and have different purposes.

Inventions of Groups III, V, and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Each of the products of III, V, and VII are independent chemical entities and require different literature searches.

Each of the products of Groups III, V, and VII are unrelated to each of the processes of Groups I, II, IV, VI, and VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Each of the processes of Groups I, II, IV, VI, and VIII do not require the products of Groups III, V, and VII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and classification, restriction for examination purposes as indicated is proper.

3. The claims are generic to a plurality of disclosed patentably distinct diseases and/or enzymes. Applicants are required to elect a single disclosed disease and/or enzyme, even though this requirement is traversed.

For Group I, the patentably distinct disease are each of the diseases recited in claim 2 and the patentably distinct enzymes are each of the enzymes recited in claim 3. If this group is elected, then Applicants must elect only one disease and only one enzyme for examination.

For Group III, the patentably distinct disease are each of the diseases recited in claim 9 and the patentably distinct enzymes are each of the enzymes recited in claim 10. If this group is elected, then Applicants must elect only one disease and only one enzyme for examination.

For Group IV, the patentably distinct disease are each of the diseases recited in claim 15 and the patentably distinct enzymes are each of the enzymes recited in claim 16. If this group is elected, then Applicants must elect only one disease and only one enzyme for examination.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF